UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

JOHN THUMANN, Plaintiff, v. ALEX AZAR, in his capacity as Secretary of the United States Department of Health and Human Services, Defendant.	:	Case No. 1:20-cv-00125 District Judge Timothy S. Black

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS AND CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

Plaintiff John Thumann suffers from an incurable form of brain cancer, glioblastoma multiforme ("GBM"). This case involves judicial review of the denial of Medicare claims by an Administrative Law Judge ("ALJ") for certain months of a device that provides tumor treatment field therapy ("TTFT") to treat GBM. The decision denying Plaintiff's claim, however, concluded that the device manufacturer would be liable for payment of the non-covered charges, not Plaintiff. Accordingly, no matter the outcome in this case, the Secretary of the Department of Health and Human Services (the "Secretary") will neither pay any money to Plaintiff nor require Plaintiff to pay any money to him. The claim denial also did not prevent Plaintiff from using the TTFT device. Since Plaintiff has therefore suffered no injury in fact from the denial of his Medicare claim, he lacks Article III standing, and the Court should dismiss this case with prejudice.

Should the Court find that Plaintiff has Article III standing, Defendant also addresses the single issue that Plaintiff raises on appeal: whether the Secretary is collaterally estopped from

denying his claims for the TTFT device because another ALJ allowed coverage for different months of the TTFT device in a prior non-precedential decision.[1] The resolution of this issue is clear: collateral estoppel does not apply. In arguing that a non-precedential ALJ decision estops the Secretary from denying Plaintiff's claim for the TTFT device, Plaintiff relies on *Astoria Federal Savings and Loan Association v. Solimino*, 501 U.S. 104 (1991), which held that administrative decisions can have preclusive effect when there is not an evident statutory purpose to the contrary. *Id*. at 108. Here, however, in the context of ALJ decisions in Medicare claim appeals, there is a statutory purpose to the contrary, as evidenced by the Medicare Act's: (1) requirement that ALJ decisions receive de novo review, (2) allowance for the Secretary to resolve claim appeals through individual adjudications, (3) requirement that claims for benefits be presented and channeled through administrative review, and (4) authorized regulations, which foreclose giving preclusive effect to ALJ decisions by specifying that such decisions are not precedential or final.

Even if there were no bar to collateral estoppel, Plaintiff would not be entitled to collateral estoppel in this case because the required elements are not met. In particular, notwithstanding that ALJ decisions in the Medicare claim appeals context are not "final" for purposes of collateral estoppel, the Secretary did not have a full and fair opportunity to litigate in the prior proceedings because it would be impracticable for the Secretary to appear as a party in the thousands of Medicare claim appeals that are filed each year at the ALJ level.

For these reasons, should the Court find that Plaintiff has Article III standing, it should grant summary judgment in the Secretary's favor and deny Plaintiff's motion.

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[1] By omission, Plaintiff has waived his right to challenge the ALJ decision at issue on the other grounds listed in his Complaint. *See Kuhn v. Washtenaw County*, 709 F.3d 612, 624 (6th Cir. 2013) ("This court has consistently held that arguments not raised in a party's opening brief, as well as arguments adverted to in only a perfunctory manner, are waived.").

II. STATUTORY AND REGULATORY BACKGROUND

A. "Reasonable and Necessary" Medicare Expenses

Medicare is a federal health insurance program for people who are elderly and/or have disabilities. *See generally*, 42 U.S.C. § 1395 *et seq*. For a medical service to be covered by Medicare, it must fit within a benefit category established by the Medicare statute. *Id*.

This case concerns Medicare Part B, which extends coverage to certain types of durable medical equipment ("DME") for qualified recipients. 42 U.S.C. §§ 1395k(a), 1395x(s)(6). Almost all Medicare coverage determinations, including those in this case, are subject to 42 U.S.C. § 1395y(a)(1)(A), which excludes certain items from coverage. Under this section, "no payment may be made under . . . part B for any expenses incurred for items or services [] which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member[.]" *Id*. The Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare program for the Secretary, has historically interpreted "reasonable and necessary" to mean that an item or service must be safe and effective, medically necessary and appropriate, and not experimental. *See* Medicare Program Integrity Manual ("MPIM") Ch. 13, § 13.5.4.[2]

The Secretary has broad discretion in administering the "reasonable and necessary" standard. *See Heckler v. Ringer*, 466 U.S. 602, 617 (1984) (citing 42 U.S.C. § 1395ff(a)). The Secretary may choose to articulate "reasonable and necessary" standards through formal regulations that have the force and effect of law throughout the administrative process. *See* 42

[2] The current MPIM is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf. The MPIM "is a compilation of guidelines which CMS issues to instruct Medicare contractors on how to conduct medical review of Medicare claims submitted by Medicare providers and suppliers for payment." *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004).

U.S.C. §§ 1395hh; 1395ff(a)(1). The Secretary may also choose to issue National Coverage Determinations ("NCDs") "with respect to whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B); *see also* 42 C.F.R. §§ 400.202, 405.1060. However, the Secretary is not required to promulgate regulations or policies that, "either by default rule or by specification, address every conceivable question" that may arise, *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 96 (1995), and may instead choose to proceed based on individual adjudications. *See Ringer*, 466 U.S. at 617.

B. Enforcement of the "Reasonable and Necessary" Standard Through Local Coverage Determinations

The Secretary has delegated to CMS broad authority to determine whether Medicare covers particular medical services. CMS, in turn, contracts with Medicare Administrative Contractors ("MACs"), such as CGS Administrators, LLC ("CGS") in this case, to administer certain day-to-day functions of the Medicare program. 42 U.S.C. § 1395kk-1. Consistent with controlling regulations and any applicable NCDs, MACs make coverage determinations, issue payments, and develop Local Coverage Determinations ("LCDs") for the geographic areas that they serve in accordance with the reasonable and necessary provision in 42 U.S.C. § 1395y(a)(1)(A). *See* 42 U.S.C. §§ 1395kk-1(a)(4), 1395ff(f)(2)(B). *See also* MPIM Ch. 13 (providing detailed guidance to MACs on how to develop LCDs). An LCD is binding only on the contractor that issued it, and only at the initial stage of the Medicare claim review process, as opposed to later stages if a beneficiary should appeal a determination by a MAC. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II). Although ALJs are not bound by LCDs, they are required to give them "substantial deference." 42 C.F.R. § 405.1062(a). If an ALJ declines to follow an LCD in a particular case, it "must explain the reasons why the policy was not followed." *Id.* at § 405.1062(b). An ALJ's decision not to

follow an LCD "applies only to the specific claim being considered and does not have precedential effect." *Id*.

C. LCDs for TTFT Devices

In April 2011, the United States Food and Drug Administration approved the commercial distribution of a TTFT device manufactured by Novocure, Inc., the NovoTTF-100A (later rebranded as "Optune"), for the treatment of recurrent GBM. Certified Administrative Record ("CAR") at 279, 283 (Doc. 6-2, PageID 322, 326). In October 2015, the DME MACs issued the original LCD for TTFT, indicating that TTFT was not covered for beneficiaries with GBM. *See id*. at 27 (PageID 70) (quoting 2015 LCD). Another LCD went into effect on January 1, 2017, and remained substantively unchanged,stating that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." *See id*. at 15-16 (PageID 58-59)..

On August 7, 2018, the DME MACs received a request from Novocure for reconsideration of the TTFT LCD, noting that it did not address newly diagnosed GBM. *See* CAR at 29 (Doc. 6-2, PageID 72) (discussing reconsideration request). Effective September 1, 2019, the LCD was revised to permit coverage for newly diagnosed GBM and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain instances. *Id*. at 115-124 (PageID 158-167). Novocure was "extremely pleased" with the 2019 LCD and noted that its coverage criteria "is generally similar to Optune's commercial coverage criteria for newly diagnosed GBM." Medicare Releases Final Local Coverage Determination Providing Coverage of Optune® for Newly Diagnosed Glioblastoma, https://www.novocure.com/medicare-releases-final-local-coverage-determination-providing-coverage-of-optune-for-newly-diagnosed-glioblastoma/ (last visited September 4, 2020).

D. Claims and Administrative Appeals

The Medicare claim process begins when the beneficiary submits a claim for payment to the MAC. *See generally*, 42 U.S.C. § 1395u(a); 42 C.F.R. § 405.920. If the claim is denied, the beneficiary must then generally exhaust the following four levels of administrative review before filing suit in district court. First, the beneficiary may seek a redetermination from the MAC, which must be performed by a person who did not make the initial decision. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. At the second level, a beneficiary may seek reconsideration by a qualified independent contractor ("QIC") whose panel members must have "sufficient medical, legal, and other expertise, including knowledge of the Medicare program." 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. §§ 405.960, 405.968(c)(1). An LCD is not binding on the QIC or at other higher levels of appeal. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.968(b). At the third level, a beneficiary can request a hearing before an ALJ, who issues a decision based on the evidence presented at the hearing or otherwise admitted into the administrative record by the ALJ. 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(d); 42 C.F.R. §§ 405.1000-02, 405.1042, 405.1046.

The administrative process ends in a *de novo* review of the ALJ's decision by the Medicare Appeals Council (the "Council"), a division of the Departmental Appeals Board of the Department of Health and Human Services. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2); 42 C.F.R. §§ 405.1100, 405.1122. The Council's decision represents the final decision of the Secretary for purposes of administrative exhaustion. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2)(A); 42 C.F.R. §§ 405.1048, 405.1130, 405.1136. However, if the Council does not render a decision within a specified time period (usually 90 days), a beneficiary may request elevation and proceed to district court without receiving a decision from the Council. 42 C.F.R. § 405.1132.

After exhausting administrative remedies, the beneficiary is entitled to judicial review of

the Secretary's decision in district court "as is provided in [42 U.S.C.] 405(g)." 42 U.S.C. § 1395ff(b)(1)(A). In such review, the Secretary's findings of fact "if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 405(g).

E. Advance Beneficiary Notices

If Medicare coverage is denied, the circumstances dictate whether Medicare, the supplier, or the beneficiary bears responsibility for payment. Medicare will pay a denied claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). If a supplier expects Medicare to deny payment, it can shift the risk of non-coverage to the beneficiary by providing him with advance written notice (called an "Advance Beneficiary Notice" or "ABN") of the specific reason why the item probably will not be covered. 42 C.F.R. § 411.404(b). The ABN helps the beneficiary decide whether to accept the financial risk of non-coverage.

In the absence of a valid ABN, a supplier cannot bill the beneficiary if Medicare coverage is denied. *See* 42 U.S.C. § 1395pp; *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 998 (9th Cir. 2012) (explaining that a valid ABN is required "for the supplier to shift liability to the beneficiary"); *California Clinical Laboratory Ass'n v. Secretary of HHS*, 104 F. Supp. 3d 66, 71-72 (D.D.C. 2015) (same).

III. STATEMENT OF FACTS

Plaintiff, who has GBM, sought coverage for the Optune device supplied by Novocure for August 2018 through October 2018. CAR at 465 (Doc. 6-3, PageID 508). The MAC CGS[3] denied payment of the claims and affirmed the initial denial on redetermination. *Id*. at 465-67 (PageID 508-10). After a QIC issued an unfavorable reconsideration decision, Plaintiff requested a hearing

[3] In the decision on appeal, ALJ Bruce MacDougall incorrectly identified the MAC as Noridian Healthcare Solutions. CAR at 52 (Doc. 6-2, Page ID 95).

before an ALJ. *Id*. at 147-48; 443-55 (Doc. 6-2; PageID 191-92; Doc. 6-3, PageID 486-498). ALJ Bruce MacDougall subsequently held a hearing in which counsel appeared for Plaintiff, but not for the Secretary. *Id*. at 52 (Doc. 6-2, PageID 95). On September 5, 2019, ALJ MacDougall issued a decision declining to deviate from the LCD for TTFT and denying Plaintiff's claims for Medicare coverage. *Id*. at 52-59 (PageID 95-102). ALJ MacDougall nevertheless concluded that Novocure, not Plaintiff, bore financial responsibility for the non-coverage because the record did not include an ABN or other indication that Plaintiff knew, or should have been expected to know, that the device would not be covered. *Id*. at 58 (PageID 101).

Following ALJ MacDougall's decision, Plaintiff appealed to the Council. CAR at 38-44 (Doc. 6-2, PageID 81-87). The Council did not issue a decision within 90 days, so Plaintiff elected to proceed to the district court pursuant to 42 C.F.R. § 405.1132. *Id*. at 1-5 (PageID 44-48).

Plaintiff's assertion that the Secretary is collaterally estopped from denying coverage in this case relies on a separate August 19, 2019 decision by ALJ Timothy Gates, who departed from the applicable LCD for TTFT and ordered coverage for the Optune device for November 2018 through January 2019. CAR at 10-18 (Doc. 6-2, PageID 53-61).[4] As was the case with the hearing before ALJ MacDougall, only counsel for Plaintiff appeared before ALJ Gates. *Id*. at 10 (PageID 53).

[4] Plaintiff also relies on a November 5, 2019 decision from ALJ Jeannie Bartlett ordering coverage for February 2019 through May 2019, and cites (but does not rely upon) a June 3, 2020 decision from ALJ Eli Bruch that is not in the CAR ordering coverage for June 2019 through August 2019. Plaintiff's Brief ("Pl.'s Br.") at 10, 11 n.6, Ex. A (Doc. 9, PageID 2393-94; Doc. 9-1). The Court should disregard these decisions because collateral estoppel may only apply if the issue was litigated in a "prior" proceeding. *Georgia-Pacific Consumer Products, LP v. Four-U-Packaging, Inc.*, 701 F.3d 1093, 1098 (6th Cir. 2012). The cases that Plaintiff cites, Pl. Br. at 3 (Doc. 9, PageID 2386), for the proposition that a later-filed case that reaches finality first may preclude an earlier-filed but still-pending case are inapposite because they concern concurrent trial-level litigation. Once a trial-level decision is reached, that decision is final (to the extent possible) even if appealed. *See Smith v. S.E.C.*, 129 F.3d 356, 362 (6th Cir. 1997) (The fact that [plaintiff] has an appeal of that judgment pending does not deprive the judgment of res judicata effect."). Regardless, the issue is moot because ALJ Gates's favorable decision preceded ALJ MacDougall's decision.

IV. STANDARD OF REVIEW

A. Motion to Dismiss

A motion to dismiss for lack of Article III standing can be brought under Rule 12(b)(1) because standing "goes to a court's subject matter jurisdiction." *Kepley v. Lanz*, 715 F.3d 969, 972 (6th Cir. 2013) (internal quotation omitted).[5] The standard of review of a 12(b)(1) motion to dismiss depends on whether the defendant makes a facial or factual challenge to subject matter jurisdiction. *Mitchell v. BMI Federal Credit Union*, 374 F. Supp. 3d 664, 667 (S.D. Oh. 2019) (citing *Wayside Church v. Van Buren County*, 847 F.3d 812, 816-17 (6th Cir. 2017)). A facial attack questions merely the sufficiency of the pleading and requires the district court to take the allegations in the complaint as true. *Id*. (quoting *Gentek Bldg. Products, Inc. v. Sherwin-Williams Co.*, 491 F.3d 320, 330 (6th Cir. 2007)). A factual attack questions whether subject matter jurisdiction actually exists and requires the court to weigh evidence, including any evidence submitted outside the pleadings, to make a determination. *Id*. (quoting *Wayside Church*, 847 F.3d at 817; *Ohio Nat'l Life Ins. Co. v. United States*, 922 F.3d 320, 325 (6th Cir. 1990)). In either case, the plaintiff has the burden of proving subject matter jurisdiction. *Id*. (citing *Rogers v. Stratton Indus.*, 798 F.2d 913, 915 (6th Cir. 1986)). This case raises a factual attack.

B. Summary Judgment

When reviewing an administrative decision regarding a claim for Medicare benefits, a court must affirm the Secretary's decision if it is supported by substantial evidence and made pursuant to the proper legal standards. *Chillicothe Chiropractic and Wellness Center v. Sibelius*, No. 2:12-cv-330, 2014 WL 1382478, at *5 (S.D. Oh. Apr. 8, 2014) (quoting *Rabbers v. Comm'r of Soc. Sec.*, 582 F.3d 647, 651 (6th Cir. 2009)); 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A). Under this

[5] Article III standing cannot be waived and may be raised at any time during a proceeding. *Zurich Ins. Co. v. Logitrans, Inc.*, 297 F.3d 528, 531 (6th Cir. 2002) (citing Fed. R. Civ. P. 12(h)(3)).

standard, substantial evidence is defined as more than a scintilla of evidence but less than a preponderance; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. *Chillicothe*, 2014 WL 1382478, at *5 (quoting *Rogers v. Comm'r of Soc. Sec.*, 486 F.3d 234, 241 (6th Cir. 2007)). The court's review is also limited to the certified administrative record. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A); *EPI Corp. v. Chater*, 91 F.3d 143, 1996 WL 428409, at *5 (6th Cir. 1996).

V. ARGUMENT

A. Plaintiff Lacks Article III Standing Because He Has Not Suffered an Injury in Fact

The U.S. Constitution limits federal court jurisdiction to actual cases or controversies. *Raines v. Byrd*, 521 U.S. 811, 818 (1997); U.S. Const. Art. III, § 2. Standing to sue is a doctrine derived from this limitation on judicial power. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). There are three elements of Article III standing, which Plaintiff has the burden to establish: (1) an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision. *Id*. at 1547 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). At the pleading stage, aplaintiff must clearly allege facts demonstrating each of these elements. *Id*. Plaintiff's complaint here, however, does not—and cannot—show that the first element of Article III standing is met.

To establish injury in fact, a plaintiff must show that he or she suffered "an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Spokeo*, 136 S. Ct. at 1548 (quoting *Lujan*, 504 U.S. at 560). A "concrete" injury must be "real" and "not abstract." *Id*. at 1548-49.

In this case, Plaintiff has not suffered a concrete injury because he was not found financially responsible for the non-coverage of the Optune device and therefore will not experience any

financial consequence regardless of the outcome of this suit. *See* CAR at 58 (Doc. 6-2, PageID # 101) (holding Novocure responsible for the non-covered charges). Indeed, the Supreme Court recently confirmed that a plaintiff who has no personal financial stake in a lawsuit has not suffered a concrete injury. *Thole v. U.S. Bank N.A.*, 140 S. Ct. 1615, 1619 (2020) (ERISA plaintiffs could not show concrete injury because they had received all of their monthly benefit payments to-date and the outcome of the suit would not affect their future benefit payments). Absent a personal financial stake in this lawsuit, Plaintiff cannot show a concrete injury because it is undisputed that his claim denials did not prevent him from using the Optune device.

Nonetheless, Plaintiff might argue that, notwithstanding financial responsibility, his statutory right to appeal a Medicare claim denial shows that the claim denial itself constitutes a concrete injury. Plaintiff would be mistaken. As explained by the *Spokeo* Court:

> Congress' role in identifying and elevating intangible harms does not mean that a plaintiff automatically satisfies the injury-in-fact requirement whenever a statute grants a person a statutory right and purports to authorize that person to sue to vindicate that right. Article III standing requires a concrete injury even in the context of a statutory violation. For that reason, [plaintiff] could not, for example, allege a bare procedural violation, divorced from any concrete harm, and satisfy the injury-in-fact requirement of Article III.

Spokeo, 136 S. Ct. at 1549. Thus, a statutory violation and corresponding right to sue does not prove the presence of a concrete injury for purposes of Article III standing. The plaintiff must still show that the statutory violation caused a concrete injury.[6] *Cf. Thole*, 140 S. Ct. at 1620-21 (rejecting that statutory right to sue under ERISA conferred Article III standing); *California Clinical Laboratory Association v. Secretary of Health and Human Services*, 104 F. Supp. 3d 66,

[6] In interpreting *Spokeo*, the Sixth Circuit recently suggested that even absent a concrete injury, a statutory violation that "created a risk of harm that Congress intended to prevent" could satisfy the injury in fact requirement. *Buchholz v. Meyer Njus Tanick PA*, 946 F.3d 855, 863 (6th Cir. 2020). However, the *Spokeo* court explained that "the risk of real harm" was just one way of showing the presence of a concrete injury. *Spokeo*, 139 S. Ct. 1549.

79 (D.D.C. 2015) (plaintiff who challenged LCD pursuant to statutory right could not show injury in fact because the LCD had not prevented her from accessing treatment or caused any financial liability due to non-coverage). In this case, since the Medicare claim denial did not cause Plaintiff to suffer a concrete injury, it is just an alleged, bare, procedural violation and it does not constitute an injury in fact.

Plaintiff might also argue that the risk of future claim denials for the Optune device, and corresponding risk that he could be financially responsible for such denials if Novocure requires him to sign an ABN, constitutes a concrete injury. However, these risks are entirely speculative. This is especially true because under the revised LCD for TTFT, claims for the Optune device with dates of service on or after September 1, 2019 may be approved by the MAC without any need for Plaintiff to appeal. CAR at 115-124 (Doc. 6-2, PageID 158-167). Speculative future harms are by definition not concrete and cannot constitute an injury in fact. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) ("injury must be certainly impending to constitute injury in fact . . . allegations of possible future injury are not sufficient.") (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)); *California Clinical*, 104 F. Supp. 3d at 79-80 (alleged risk of future injury due to unfavorable LCD was not concrete because it was speculative that the plaintiff would be prescribed the treatment at issue, that Medicare would again deny coverage, and that the plaintiff would be given an ABN such that she could bear financial responsibility for non-coverage).

Plaintiff may finally argue that if the Secretary prevails in this appeal, then Novocure might bill him for the cost of the Optune device. However, Plaintiff has not alleged that a bill from Novocure is impending, and as addressed above, Novocure does not meet the requirement to validly bill Plaintiff because it did not provide him with an ABN. CAR at 58 (Doc. 6-2, PageID # 101). Accordingly, the possibility that Novocure might try to bill Plaintiff for the cost of the Optune

device is similarly too speculative to constitute a concrete injury.[7]

In sum, because Plaintiff was not found financially responsible for the non-covered charges, he cannot show that his Medicare claim denial caused him to suffer a concrete injury. Plaintiff therefore cannot satisfy the injury in fact element of Article III standing, and this case should be dismissed with prejudice. *Cf. Pehoviack v. Azar*, No. SA CV 20-00661, 2020 WL 4810961 (C.D. Cal. Jul. 22, 2020), *appeal docketed*, No. 20-55841 (9th Cir. Aug. 17, 2020) (in similar appeal of the denial of Medicare coverage for the Optune device, holding that plaintiff lacked standing because she had not suffered an injury in fact; dismissing without leave to amend); *Komatsu v. Azar*, SACV 20-00280, 2020 WL 5814116 (C.D. Cal. Sept. 24, 2020), *appeal docketed*, No. 56001 (9th Cir. Sept. 29, 2020) (same).

B. The Secretary Is Not Collaterally Estopped From Denying Plaintiff's Claim

Even if Plaintiff has Article III standing, the Secretary is still entitled to summary judgment because Plaintiff's sole argument on appeal—that a prior favorable ALJ decision estops the Secretary from denying coverage—fails. This is so for two reasons. First, ALJ decisions in the Medicare claim appeals context are not entitled to preclusive effect. Second, the elements of collateral estoppel are not met.

1. ALJ Decisions in the Medicare Claim Appeals Context Are Not Entitled to Preclusive Effect.

Under *Astoria Federal Savings and Loan Association v. Solimino*, 501 U.S. 104 (1991),

[7] Even if Novocure announced its intent to bill Plaintiff should the Secretary prevail, any injury that Plaintiff suffers after this case is over cannot create standing because standing must be assessed "at the outset of the litigation." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180 (2000). Additionally, this injury would not be fairly traceable to the Secretary or capable of being redressed by a favorable decision because Novocure has complete discretion as to whether to bill Plaintiff for his treatment. *See Lujan*, 540 U.S. at 560 (an injury cannot be the "result of independent action of some third party not before the court.").

the presumption that decisions issued by administrative agencies have preclusive effect is overcome "when a statutory purpose to the contrary is evident." *Id*. at 108. A statutory purpose to the contrary may be evidenced either expressly or implicitly. *Astoria*, 501 U.S. at 108-110.[8] In this case, in the context of ALJ decisions in Medicare claim appeals, a statutory purpose to the contrary is evidenced in four ways.

First, the Medicare Act requires the Council to review ALJ decisions *de novo*. 42 U.S.C. § 1395ff(d)(2)(B). If a favorable ALJ ruling collaterally estopped the Council from denying a beneficiary's claim for the same treatment, then the Council could not perform a de novo review; instead, the Council would be bound to accept the ALJ's conclusions. *See Almy v. Sebelius*, 679 F.3d 297, 310 (4th Cir. 2012) (Council's requirement to perform *de novo* review is incompatible with prospect of deferring to outcomes of ALJ decisions below); *Bigure v. Hansen*, No. 1:16-cv-808, 2017 WL 25503, at *3 (S.D. Oh. Jan. 3, 2017) (Black, J.) (requirement that district court review a naturalization denial *de novo* foreclosed giving preclusive effect to immigration judge's findings).

Second, the Secretary has discretion under the Medicare Act to implement the "reasonable and necessary" standard through individual adjudications. *Heckler v. Ringer*, 466 U.S. 602, 617 (1984); *see also Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 97 (1995) ("The Secretary's mode of determining benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate."). Under Plaintiff's theory, once one ALJ approved a claim for benefits,

[8] Plaintiff's citation to *U.S. v. Texas*, 507 U.S. 529, 534 (1993), Pl.'s Br. at 4 (Doc. 9, PageID 2387), for the proposition that a statute must speak directly to the question addressed by the common law is inapposite because that case, unlike *Astoria*, did not specifically address collateral estoppel. Additionally, the *Texas* Court in fact endorsed Congress' ability to implicitly evidence a statutory purpose to the contrary of a common law principle, stating "[w]e agree with Texas that Congress need not affirmatively proscribe the common-law doctrine at issue." *Id.* (internal quotation omitted).

future ALJs would not be permitted to reach the opposite conclusion, thus depriving them of the ability to individually adjudicate the claim at issue.[9]

Third, the Medicare Act requires that all claims for benefits be presented and channeled through administrative review. *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 12 (2000) (citing *Ringer*, 461 U.S. at 614). If the Secretary were collaterally estopped from denying Plaintiff's claims for the Optune device, then Plaintiff would be establishing an entitlement to future Medicare benefits for the Optune device even though claims for those benefits have not yet been presented or channeled.[10] *See Porzecanski v. Azar*, 943 F.3d 472, 482-83 (D.C. Cir. 2019) (rejecting plaintiff's request for prospective equitable relief mandating that the Secretary recognize his treatment as a covered Medicare benefit in all future claim determinations because this would violate the presentment and channeling requirement).

Finally, the Medicare Act confers the Secretary with broad authority to promulgate regulations, 42 U.S.C. §§ 1395ff(a)(1), 1395hh, and these regulations foreclose the possibility that ALJ decisions in the Medicare claim appeals context can have any preclusive effect. In particular, the regulations specify that only Council-level decisions have the potential to become precedential (*i.e.*, binding in future cases). 42 C.F.R. § 401.109; *see also* 42 C.F.R. §§ 405.968(b) (omitting ALJ decisions from rulings that bind the QIC), 405.1062(b) (ALJ decisions that depart from LCDs apply only to the specific claim being considered and have no precedential effect). If an ALJ decision has no precedential effect and is not binding on future parties, then it cannot have

[9] Plaintiff has also not articulated any reason, should ALJ decisions be entitled to preclusive effect, why the first *denial* of benefits should not correspondingly estop the beneficiary from making future attempts to secure Medicare coverage. The absurdity of this outcome further illustrates that the Medicare Act's allowance for individual adjudications is incompatible with giving preclusive effect to ALJ decisions.

[10] Plaintiff explicitly requests a finding that the Secretary is collaterally estopped from denying his Medicare claim, as opposed to a finding that the ALJ's decision was unsupported by substantial evidence, in order to circumvent future participation in the Medicare claim appeals process. Pl.'s Br. at 2 (Doc. 9, PageID 2385).

preclusive effect for purposes of collateral estoppel. *See Christenson v. Azar*, No. 20-cv-194, 2020 WL 3642315, at *6 (E.D. Wis. Jul. 6, 2020)[11] ("If a decision is deemed not to have 'precedential effect' on the *same* parties in the future, it necessarily forecloses when and where collateral estoppel can apply.") (emphasis original).

The Secretary's regulations further specify that ALJ decisions do not constitute the "final" decision of the Secretary. *Cf*. 42 C.F.R. §§ 405.1130 (Council's decision is "*final* and binding on all parties") (emphasis added), 405.1048 (ALJ's decision is "binding on all parties"). The Secretary's determination that ALJ decisions are not "final" is conclusive for purposes of collateral estoppel. *See* Restatement (Second) of Judgments § 13 (1982)[12] ("final judgment" for purposes of collateral estoppel means "any prior adjudication of an issue in another action *that is determined to be sufficiently firm to be accorded conclusive effect.*") (emphasis added); *Christenson*, 2020 WL 3642315, at *6 ("In the administrative realm, it is not unreasonable or arbitrary for the Secretary to decide what stage deserves preclusive effect."); *see also*, *id*. ("It is difficult to conclude that, within the multi-layer scheme of internal claim review administered by the Secretary, the early stage of ALJ review is the point at which an issue becomes final for purposes of collateral estoppel.").[13]

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[11] *Christenson* is similarly an appeal of an ALJ decision denying coverage for the Optune device.

[12] The Supreme Court "regularly turns to the Restatement (Second) of Judgments for a statement of the ordinary elements of issue preclusion." *B & B Hardware, Inc. v. Hargis Industries, Inc.*, 575 U.S. 138, 148 (2015).

[13] Plaintiff's citations in support of the proposition that ALJ decisions are final, Pl.'s Br. at 17-18 (Doc. 9, PageID 2400-01), are inapposite. First, 70 Fed.Reg. 36386-7 (June 23, 2005) lacks the force and effect of law and is just a statement of organization for the Office of Medicare Hearings and Appeals. In contrast, 42 C.F.R. § 405.1048 specifically addresses the effect of an ALJ's decision. Second, while *Smith v. Berryhill*, 139 S. Ct. 1765, 1775-76 (2019) addresses finality for purposes of appeal to federal court, it does not address finality for purposes of issue preclusion.

Given these considerations, it is no surprise that many Circuit courts have unanimously acknowledged that ALJ decisions in the Medicare claim appeals context have no preclusive effect.[14] *See, e.g.*, *Almy*, 679 F.3d at 310-11 (only Council-level decisions constitute the final decision of the Secretary; plaintiff's proposed expansion of what constitutes binding precedent would severely constrict administration of the Medicare program; lower-level decisions cannot bind the Secretary just as lower courts cannot bind the Supreme Court); *Porzecanski*, 943 F.3d at 477 ("[A] favorable determination in one proceeding does not ensure that future claims will be approved."); *Taransky v. Secretary of U.S. Dept. of Health and Human Services*, 760 F.3d 307, 319 (3rd Cir. 2014) (Council owes no deference to and is not bound by ALJs); *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012) (adopting reasoning in *Almy*); *Abraham Mem. Hosp. v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012) ("Our precedent instructs that Board decisions are not decisions of the Secretary . . . and are not authoritative.");[15] *Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) ("[T]he decision of the [Provider Reimbursement Review Board] carries no more weight on review by the Secretary than any other interim decision made along the way in an agency where the ultimate decision of the agency is controlling.").

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[14] Plaintiff's citations for the proposition that agency determinations can have preclusive effect, Pl.'s Br. at 5 (Doc. 9, PageID 2388), are inapposite because none involve an ALJ decision in the Medicare claim appeals context. The only case that implicates Medicare at all, *DeWall Enterprises, Inc. v. Thompson*, 206 F. Supp. 2d 992 (D. Neb. 2002), involved a dispute over the proper coding for an orthotics device. After four ALJs found that the code used by DeWall was appropriate (and none of those decisions were appealed), the MAC again determined that the code used by DeWall was inappropriate. In rejecting the Secretary's argument that the MAC was free to interpret the code differently because ALJ decisions are not precedential, the district court wrote: "[t]he Secretary's assertions that the ALJ's decisions are not afforded any preclusive effect are without merit." *Id.* at 1001. In this context, the court simply meant that the Secretary was required to implement the un-appealed ALJ decisions. *DeWall* did not address whether an ALJ decision adjudicating the "reasonable and necessary" standard could have preclusive effect on a subsequent ALJ decision.

[15] *Abraham Mem. Hosp.* involved a decision of the Provider Reimbursement Review Board, an administrative appellate body for Medicare Part A appeals, similar to an ALJ in Part B administrative appeals. 42 U.S.C. § 1395oo.

In sum, the Medicare Act: (1) requires de novo review of ALJ decisions, (2) affords the Secretary the right to implement the "reasonable and necessary" standard through individual adjudication, (3) requires claims for benefits to be presented and channeled through administrative review, and (4) authorizes regulations, which foreclose giving preclusive effect to ALJ decisions. As recognized by courts in the Third, Fourth, Fifth, Seventh, Ninth, and DC circuits, all of these aspects of the Medicare Act are incompatible with giving preclusive effect to ALJ decisions in the context of Medicare claim appeals. The Medicare Act therefore evidences a statutory purpose to the contrary of giving such preclusive effect, so the Secretary cannot be collaterally estopped from denying coverage in this case.[16] *Cf*. *Christenson*, 2020 WL 3642315, at *4-7 (E.D. Wis. Jul. 6, 2020) (holding that Medicare's administrative review structure was incompatible with applying collateral estoppel on the basis of ALJ-level decisions).

2. Even if Collateral Estoppel Were Possible, the Elements are Not Met.

Even if ALJ decisions in the Medicare claim appeals context were capable of having preclusive effect, Plaintiff's request to estop the Secretary from denying coverage in this case still fails because the elements of collateral estoppel are not met. When collateral estoppel is possible, it applies when: (1) the precise issue was raised and actually litigated in the prior proceedings; (2) the determination of the issue was necessary to the outcome of the prior proceedings; (3) the prior proceeding resulted in a final judgment on the merits; and (4) the party against whom estoppel is sought had a full and fair opportunity to litigate the issue in the prior proceeding. *Georgia-Pacific Consumer Products, LP v. Four-U-Packaging, Inc.*, 701 F.3d 1093, 1098 (6th Cir. 2012). In this

[16] To the extent Plaintiff's request to collaterally estop the Secretary is grounded in concerns about the need to re-litigate whether the provision of TTFT through the Optune device is a covered Medicare benefit, Defendant notes that Plaintiff could have used separate channels of review to challenge the applicable LCD for TTFT or to petition CMS for an NCD. *See* 42 U.S.C. § 1395y(1) (describing process of requesting an NCD); 42 C.F.R. Part 426, Subpart D (describing process for challenging an LCD).

case, notwithstanding that Plaintiff cannot satisfy the third element because, as addressed above, ALJ decisions are not "final" for purposes of collateral estoppel, Plaintiff cannot satisfy the fourth element because the Secretary did not have a full and fair opportunity to litigate in the prior proceeding that Plaintiff relies upon.

Plaintiff asserts that the Secretary had a full and fair opportunity to litigate in the prior proceeding because counsel for the Secretary had the right to appear, even though counsel did not in fact appear. Pl.'s Br. at 14, 18 (Doc. 9, PageID 2397, 2401); *see* 42 C.F.R. § 405.1012 (Secretary permitted to appear at ALJ hearings when beneficiary is represented by counsel); CAR at 10 (Doc. 6-2, PageID 53) (only counsel for Plaintiff appeared at hearing before ALJ Gates). However, what Plaintiff overlooks is that there are thousands of ALJ appeals filed each year, so the Secretary cannot possibly appear in every one. *See, e.g.*, *Am. Hosp. Assoc. v. Azar*, 14-cv-851, Dkt. No. 98 (D.D.C. June 26, 2020 Status Report) (43,887 ALJ appeals received in Fiscal Year 2019); *Christenson*, 2020 WL 3642315, at *7 ("even several thousand beneficiary appeals filed annually makes it virtually impossible for the Secretary to be represented at every ALJ-level hearing."). Given the practical impossibility for the Secretary to appear in every ALJ appeal, the Secretary only has a full and fair opportunity to litigate if he actually appears—which in this case, he did not.[17] Plaintiff therefore cannot establish the fourth element of collateral estoppel.

In sum, even if ALJ decisions in the Medicare claim appeals context were capable of having

[17] Plaintiff's citations, Pl.'s Br. at 14 (Doc. 9, PageID 2397), for the proposition that the Secretary had a full and fair opportunity to litigate even though he did not appear are inapposite. Neither *Meyer v. Rigdon*, 36 F.3d 1375 (7th Cir. 1994) nor *EZ Loader Boat Trailers, Inc. v. Cox Trailers, Inc.*, 746 F.2d 375 (7th Cir. 1984) involved the potential application of collateral estoppel against the government. Additionally, in *Meyer*, a default judgment was only accorded preclusive effect because the doctrine of collateral estoppel had been expanded by the Bankruptcy Code, while in *EZ Loader*, the party against whom collateral estoppel was to be applied in fact had representation in the prior proceeding. *Meyer*, 36 F.3d at 1379-82; *EZ Loader*, *746* F.2d at 378.

preclusive effect, the decision by ALJ Gates relied upon by Plaintiff in this case would not qualify because the Secretary lacked a full and fair opportunity to litigate in that proceeding. This is further reason why the Secretary is not collaterally estopped from denying coverage in this case.[18]

VI. CONCLUSION

For these reasons, Plaintiff lacks Article III standing because he has not suffered an injury in fact. Since Plaintiff cannot cure this defect by amendment, the Court should dismiss this case with prejudice.

Should the Court find that Plaintiff has Article III standing, then the Court should grant summary judgment in the Secretary's favor and deny Plaintiff's motion for summary judgment because ALJ decisions in the Medicare claim appeals context are not capable of having preclusive effect, and even if they were, the elements for collateral estoppel are not met in this case.

Respectfully submitted,

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[18] Even if ALJ Gates's decision were entitled to preclusive effect, Plaintiff would only be able to rely upon it for claims for the Optune device with dates of service before September 1, 2019 due to the revised LCD for TTFT. *See Montana v. United States*, 440 U.S. 147, 155 (1979) (collateral estoppel will not apply when "controlling facts or legal principles have changed significantly since the [prior] judgment.").